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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

KRUSE, DAVID H

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/804,219	Applicant(s) CHAUDHARY ET AL.	
	Examiner David H. Kruse	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 October 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 7-22, 25-35, 67-70 and 72-74 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 7-22, 25-35, 67-70 and 72-74 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

STATUS OF THE APPLICATION

1. This Office action is in response to the Amendments filed 8 October 2008 and the Remarks filed 17 June 2008.
2. Those objections or rejections not specifically addressed in this Office action are withdrawn in view of Applicants' amendments to the claims.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

4. Claims 18 and 72-74 remain rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection is repeated for the reason of record as set forth in the last Office action mailed 17 January 2008.

Applicant's arguments filed 17 June 2008 have been fully considered but they are not persuasive.

Claim 18 remains indefinite because it recites at lines 3-4 "a nucleic acid sequence that is complementary" in limiting the promoter used in the method of claim 1, yet it is unclear how a complementary sequence of a promoter would function in the method of claim 1. Hence, the metes and bounds of the claim are unclear. Applicants argue that the specification makes clear that a complement can be a seed specific-promoter at paragraph number [0102] (page 10, 1st paragraph of the Remarks). This argument is not found persuasive. First, the instant specification does not contain numbered paragraphs, and it is unclear where in the specification Applicants are

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referring. In addition, Applicants do not teach that the promoter sequence of instant SEQ ID NO: 6 can function as a bi-directional promoter, hence it does not appear that a complementary sequence would function as such. The rejection is maintained.

Claims 18 and 72-74 remain indefinite because, Applicants teach at page 8, line 26 that the ABRE sequence consists of (G/C/T)ACGT(G/T)GC, but SEQ ID NO: 6 does not comprise this ABRE sequence, Applicants teach a "G box" in Figure 3-1 which has the sequence CACGTGTA. Hence, the metes and bounds of the claims are unclear because SEQ ID NO: 6 does not appear to comprise the required structure. Applicants argue that an ABRE element may be found in SEQ ID NO: 6 between nucleotides 253 and 257 (page 10, 3rd paragraph of the Remarks). This argument is not found to be persuasive because nucleotides 252-260 is - TACGTGTAA – which fails to teach an ABRE sequence consistent with the specification.

5. Claims 1-4, 7-22, 25-35 and 67-74 remain rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is repeated for the reason of record as set forth in the last Office action mailed 17 January 2008. Applicant's arguments filed 17 June 2008 have been fully considered but they are not persuasive.

Applicants argue that SEQ ID NO: 6 does indeed comprise an RY Repeat. Applicants argue that as disclosed in paragraph number [060], "the RY promoter

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element is defined as a promoter element having a sequence of CATGCA in accordance with the consensus sequence for RY promoter elements as discussed by Dickenson *et al.* (1988) *Nuc. Acids Res.* 16:371." Applicants argue that an RY element having the sequence CATGCA can be found in SEQ ID NO: 6 at base pairs 285-290 (paragraph spanning pages 10-11 of the Remarks). Applicants argue that an ABRE element may be found in SEQ ID NO: 6 between nucleotides 253 and 257 (page 11, 2nd paragraph of the Remarks). Applicants argue that with respect to SEQ ID NO: 6, the as-filed specification enables sequences that are complementary, sequences that have substantial sequence homology, and sequences that are analogs of SEQ ID NO: 6. Applicants argue that with respect to sequences that hybridize under stringent conditions to recited sequences, the as-filed application provides sufficient guidance to enable one of skill in the art to prepare such sequences. Applicants argue that only a routine amount of work would be required for someone skilled in the art to design suitable sequences and assess their hybridization under the recited stringent hybridization conditions (page 11, 4th paragraph of the Remarks). These arguments are not found to be persuasive. The art teaches that an RY element is a repeat octamer of CATGCATG (see Reidt *et al* 2000, page 402, right column; and Bobb *et al* 1997, page 643, right column, second to last paragraph). In instant Figure 3-1(SEQ ID NO: 6), Applicants refer in Figure 3-1 to an RY element as having the sequence [C]ATGAATA and a seed-specific element CATGCA, and at page 8, line 9 of the specification Applicants refer to an RY element as CATGCA. Nucleotides 252-260 of SEQ ID NO: 6 is - TACGTGTAA – which fails to describe an ABRE sequence consistent with the

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specification which at page 8, line 26 states that the ABRE sequence consists of (G/C/T)ACGT(G/T)GC, but SEQ ID NO: 6 does not comprise this ABRE sequence. Applicants' arguments concerning enablement is not relevant to the instant rejection directed to adequate Written Description. Given the facts, it is the Examiner's opinion that one of skill in the instant art would not have viewed Applicants as having possession of the invention as broadly claimed.

6. Claims 1-4, 7-22, 25-35 and 67-74 remain rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for a method of using an isolated nucleic acid molecule comprising a nucleic acid sequence comprising bases 1-417 of SEQ ID NO: 6 having seed-preferred promoter activity and a transgenic plant transformed therewith, does not reasonably provide enablement for a genus of seed-specific promoters obtained from flax comprising an RY repeat and an ABRE promoter element or an isolated nucleic acid molecule that hybridizes under stringent hybridization conditions to a nucleic acid molecule having the sequence of SEQ ID NO: 6. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. This rejection is repeated for the reason of record as set forth in the last Office action mailed 17 January 2008. Applicant's arguments filed 17 June 2008 have been fully considered but they are not persuasive.

Applicants argue that the application discloses at least four examples of seed-specific promoters, each of which comprise an RY repeat and an ABRE promoter element. Applicants argue that the nucleic acid sequences of the four promoters are

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provided in the application in SEQ ID NO: 1, SEQ ID NO: 4, SEQ ID NO: 6, and SEQ ID NO: 8. Applicants argue that the as-filed specification describes a representative number of nucleotide sequences (*e.g.* SEQ ID NOs: 1, 4, 6, and 8) as well as the structural features common to the members of the genus (*e.g.* an RY repeat and ABRE promoter element) for the seed-specific promoters defined in the claims. Applicants argue that they have properly described the genus of seed-specific promoters recited in the claims. Applicants argue that they have taught how to make and use the genus of seed-specific promoters recited in the instant claims. Applicants argue that with respect to SEQ ID NO: 6, the as-filed specification enables sequences that are complementary, sequences that have substantial sequence homology, and sequences that are analogs of SEQ ID NO: 6. Applicants argue that with respect to sequences that hybridize under stringent conditions to recited sequences, the as-filed application provides sufficient guidance to enable one of skill in the art to prepare such sequences. Applicants argue that only a routine amount of work would be required for someone skilled in the art to design suitable sequences and assess their hybridization under the recited stringent hybridization conditions (page 12 of the Remarks). These arguments are not found to be persuasive. It remains the Examiner's opinion that it is unclear that Applicants have taught how to make and use the genus of "seed-specific promoter(s) obtained from flax" comprising a RY repeat and an ABRE promoter element as broadly claimed. Given the evidence of record, it is unclear that SEQ ID NO: 6 represents even one species of the promoters to be used in the claimed method. The Examiner has outlined the teachings

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of the art at the time of Applicants' invention in the previous Office action mailed 17 January 2008.

Double Patenting

7. Claims 18 and 72-74 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,777,591.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the promoter of SEQ ID NO: 8 in the issued patent, claim 1, is asserted by Applicants to comprise the promoter elements of the instant claim 1.

Applicants state that they respectfully defer this issue until the application is otherwise in condition for allowance (page 12 of the Remarks). Applicants' statement is noted, but the rejection is maintained.

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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9. No claims are allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (571) 272-0799. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached at (571) 272-0975. The central FAX number for official correspondence is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (571) 272-1600.

/David H Kruse/
Primary Examiner, Art Unit 1638
10 December 2008